

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

In re Application of:)	
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FRIGG et al.)	
)	
Serial No.: 10/532,909)	Group Art Unit: 3775
)	
Filed: December 16, 2005)	Examiner: N. Woodall
)	
For: DEVICE FOR THE TREATMENT OF FRACTURES OF THE FEMUR)	Board of Patent Appeals and Interferences
)	
Confirmation No.: 3108)	
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REPLY BRIEF UNDER 37 C.F.R. § 41.41

In response to the Examiner's Answer mailed on November 9, 2009 to the Appeal Brief filed on August 3, 2009, and pursuant to 37 C.F.R. § 41.41, Appellants present this reply brief in the above-captioned application.

This is an appeal to the Board of Patent Appeals and Interferences from the Examiner's final rejection of claims 19 - 40 in the Final Office Action dated November 18, 2008 as clarified in the Advisory Action dated March 3, 2009. The appealed claims are set forth in the attached Claims Appendix.

1. Status of the Claims

Claims 19 - 40 have been rejected in the Final Office Action, and are the subject of the present appeal.

2. Grounds of Rejection to be Reviewed on Appeal

- I. Whether claims 19 - 25, 27, 31, 34 - 38, and 40 are unpatentable under 35 U.S.C. § 103(a) over United States Patent No. 5,032,125 to Durham ("Durham") in view of United States Patent No. 5,454,813 to Lawes ("Lawes").
- II. Whether claim 27 is unpatentable under 35 U.S.C. § 103(a) over Durham in view of Lawes and United States Patent No. 6,648,889 to Bramlet et al. ("Bramlet").
- III. Whether claims 28 and 29 are unpatentable under 35 U.S.C. § 103(a) over Durham in view of Lawes and United States Patent No. 4,432,358 to Fixel ("Fixel").
- IV. Whether claims 30, 32, and 39 are unpatentable under 35 U.S.C. § 103(a) over Durham in view of Lawes and United States Patent No. 5,908,422 to Bresina ("Bresina").
- V. Whether claim 33 is unpatentable under 35 U.S.C. § 103(a) over Durham in view of Lawes, Bresina, and United States Patent No. 6,187,007 to Frigg et al. ("Frigg").

3. Argument

- I. The Rejection of Claims 19 - 25, 27, 31, 34 - 38 and 40 as Obvious Over Durham in View of Lawes Should be Reversed

A. The Examiner's Rejection

In the Final Office Action, claims 19 - 25, 27, 31, 34 - 38 and 40 were rejected under 35 U.S.C. § 103(a) as obvious over Durham in view of Lawes. *11/18/08 Office Action*, p. 2.

- B. The References Do Not Disclose an Interior Surface Profile of a Sliding Sleeve Configured to Receive the Shaft of a Bone Fixation Element While Permitting Free Rotation of the Bone Fixation Element Relative to the Sleeve and a Locking

Mechanism to Selectively Lock Rotation of the
Bone Fixation Element Relative to the Sleeve as
Recited in Claims 19 and 37

Claim 19 recites a device for the treatment of femoral fractures comprising “an intramedullary pin having a first longitudinal axis, a proximal portion, a distal portion, and at least one transverse opening through the proximal portion of the pin, the at least one transverse opening forming an oblique angle with the first longitudinal axis and having a non-circular cross-section” and “a bone fixation element having a second longitudinal axis, a first end, a second end, and a shaft, the first end configured and dimensioned to engage bone in the femoral head” in combination with “a sliding sleeve having a central bore, an interior surface profile, and an exterior surface profile, *the central bore and interior surface profile configured to receive the shaft of the bone fixation element while permitting free rotation of the bone fixation element relative to the sleeve*, and the exterior surface profile having at least a portion with a non-circular cross-section adapted to mate with the non-circular cross-section of the transverse opening, thereby prevention rotation of the sleeve with respect to the intramedullary pin” and “*a locking mechanism configured and adapted to selectively lock rotation of the bone fixation element relative to the sleeve when in a first position and permit free rotation of the bone fixation element relative to the sleeve when in a second position.*”

In contrast, it is respectfully submitted that Durham discloses a lag screw and sleeve that are keyed to one another such that the lag screw and the sleeve cannot be rotated relative to one another. Since the lag screw and the sleeve can never be rotated relative to one another, it also follows that Durham does not show or suggest a locking mechanism that selectively locks and permits rotation of the lag screw and the sleeve. Specifically, Durham describes a sleeve 40 that slidably receives a lag screw 60. *Durham*, col. 3, ll. 19 - 22. The sleeve 40 includes a bore 42

that is keyed such that the bore 42 includes opposing flat surfaces 44. *Id.* at col. 3, ll. 61 - 63. The lag screw 60 includes an elongated body member 62 that is also keyed with opposing flat surfaces 66 which complement and cooperate with the flat surfaces 44 of the sleeve 40. *Id.* at col. 3, l. 66 - col. 4, l. 2. Thus, the surfaces 44, 66 cooperate to prevent lag screw 60 from rotating within sleeve 40 while permitting lag screw 60 to slide axially within sleeve 40. *Id.* at col. 4, ll. 3 - 6. Therefore, it is respectfully submitted that Durham does not show or suggest that the sleeve 40 and the lag screw 60 are rotatable relative to one another.

The Examiner, however, asserts that the embodiments described by Durham are preferred embodiments and do not necessarily encompass all the variations of the invention. *Examiner's Answer*, p. 8. The Examiner notes that Durham states that the sleeve "may" include an engaging surface on the interior surface of the sleeve and interprets this language of Durham as implying that the device is not required to include the engagement surfaces. *Id.* at p. 9. The Examiner further states that the engagement surfaces are not disclosed as being critical to the function of the device and are capable of being modified without destroying the reference as suggested by Durham. *Id.* Appellants respectfully disagree. It is respectfully submitted that it would be understood by those of skill in the art that in order to attain proper reduction of a fracture of a hip, the lag screw 60 which fixes a head of the femur relative to a shaft portion of the femur, should not be rotatable relative to the shaft portion of the femur, once fixed, and should thus be prevented from rotating relative to the sleeve 40. Durham does not show or suggest anywhere in the specification that the lag screw 60 should be rotatable relative to sleeve 40 when received therein nor does Durham include any other features that would selectively prevent the lag screw 60 from rotating relative to the sleeve 40 once it is in a desired position. Indeed, Durham clearly teaches that the lag screw 60 is axially slidable relative to the sleeve 40 without rotating relative

thereto to provide sliding compression. *Durham* at col. 4, ll. 3 - 6. In particular, the combination of the lag screw 60, the sleeve 40 and a compression screw 90 applies a sliding compressive force to selected fractures of a femur. *Id.* at col. 4, ll. 18 - 20 and 29 - 32. Thus, it is respectfully submitted that the “may” language of *Durham* does not imply that the structural features preventing rotation of the sleeve 40 and the lag screw 60 relative to one another are optional. Rather, it is respectfully submitted that the “may” would be understood by those of ordinary skill in the art as indicating that other structures can be used in place of the opposing surfaces 44, 66 of the sleeve 40 and the lag screw 60, respectively, to similarly prevent rotation of the sleeve 40 relative to the lag screw 60.

Furthermore, the Examiner contends that the compression screw 90 is comparable to the locking mechanism of the recited claim. *11/18/08 Office Action*, p. 2. The compression screw 90, however, does not include any features that would prevent the lag screw 60 from rotating relative to the sleeve 40. The compression screw 90 includes a threaded shank 92 that is engaged with a threaded bore 68 of the lag screw 60 and a head 94 that presses against the sleeve 40 to prevent the lag screw 60 from sliding any further distally through the sleeve 40 once the lag screw 60 and the compression screw 90 are engaged. *Id.* at col. 4, ll. 15 - 32. *Durham* does not teach or suggest that the compression screw 90 includes any feature that would prevent rotation of the lag screw 60 relative to the sleeve 40 if the lag screw 60 and the sleeve 40 including correspondingly circular surfaces. Indeed, as shown in Fig. 6, the head 94 is flat-bottomed such that the head 94 merely abuts an end of the sleeve 40 when slid distally therethrough such that if the sleeve 40 and the lag screw 60 included circular surfaces, the lag screw 60 would freely slide and rotate within the sleeve 40 even when engaged with the compression screw 90. *Id.* at col. 4, ll. 21 - 29. Thus, it is respectfully submitted that *Durham* does not show or suggest that the lag

screw 60 is ever rotatable relative to the shaft 40 and further does not show or suggest that the compression screw 90 includes any feature to selectively lock the lag screw 60 relative to the sleeve 40.

It is respectfully submitted that Lawes does not cure this deficiency of Durham. Accordingly, it is respectfully submitted that neither Durham nor Lawes, either alone or in combination, show or suggest “*the central bore and interior surface profile configured to receive the shaft of the bone fixation element while permitting free rotation of the bone fixation element relative to the sleeve*” and “*a locking mechanism configured and adapted to selectively lock rotation of the bone fixation element relative to the sleeve when in a first position and permit free rotation of the bone fixation element relative to the sleeve when in a second position,*” as recited in claim 19. Thus, it is respectfully submitted that claim 19 is not rendered obvious by Durham in view of Lawes and that the final rejection of this claim should be reversed. Because claims 20 - 25, 27, 31 and 34 - 36 depend from and include all of the limitations of claim 19, it is respectfully submitted that these claims are also allowable.

Similarly, claim 37 recites a device for the treatment of femoral fractures comprising “an intramedullary pin having a first longitudinal axis, a proximal portion, a distal portion, and at least one transverse opening through the proximal portion of the pin, the at least one transverse opening forming an oblique angle with the first longitudinal axis and having a non-circular cross-section” and “a cross-member configured for insertion through the transverse opening to engage bone in the femoral head, the cross-member” including “a sliding sleeve having a central bore, a circular interior surface profile, and a non-circular exterior surface profile, the exterior surface profile adapted to mate with the non-circular cross-section of the transverse opening, thereby

preventing rotation of the sleeve with respect to the intramedullary pin” and “a bone fixation element having a first end, a second end, and a shaft, the first end configured and dimensioned to engage bone in the femoral head, and *the shaft configured and dimensioned for free rotation within the central bore of the sliding sleeve*” along with “a locking mechanism configured and adapted to selectively lock rotation of the bone fixing element relative to the sleeve when in a first position and permit free rotation of the bone fixing element relative to the sleeve when in a second position.”

For at least the same reasons as discussed above in regard to claim 19, it is respectfully submitted that claim 37 is not rendered obvious by Durham in view of Lawes and that the rejection of this claim should be reversed. Because claims 38 and 40 depend from and include all of the limitation of claim 37, it is respectfully submitted that these claims are also allowable.

II. The Rejection of Claim 27 as Obvious Over Durham in View of Lawes and Further in View of Bramlet Should be Reversed

A. The Examiner's Rejection

In the Final Office Action, claim 27 was rejected under 35 U.S.C. § 103(a) as obvious over Durham in view of Lawes and further in view of Bramlet. *11/18/08 Office Action*, p. 4.

B. The References Do Not Disclose an Interior Surface Profile of a Sliding Sleeve Configured to Receive the Shaft of a Bone Fixation Element While Permitting Free Rotation of the Bone Fixation Element Relative to the Sleeve and a Locking Mechanism to Selectively Lock Rotation of the Bone Fixation Element Relative to the Sleeve as Recited in Claim 19

It is respectfully submitted that Bramlet does not cure the deficiencies of Durham in view of Lawes as discussed above in regard to claim 19. Since claim 27 depends from and includes all of the limitations of claim 19, it is respectfully submitted that this claim is not rendered obvious

by Durham in view of Lawes and in further view of Bramlet and that the rejection of this claim should be reversed.

III. The Rejection of Claims 28 and 29 as Obvious Over Durham in View of Lawes and Further in View of Fixel Should be Reversed

A. The Examiner's Rejection

In the Final Office Action, claims 28 and 29 were rejected under 35 U.S.C. § 103(a) as obvious over Durham in view of Lawes and further in view of Bramlet. *11/18/08 Office Action*, p. 5.

B. The References Do Not Disclose an Interior Surface Profile of a Sliding Sleeve Configured to Receive the Shaft of a Bone Fixation Element While Permitting Free Rotation of the Bone Fixation Element Relative to the Sleeve and a Locking Mechanism to Selectively Lock Rotation of the Bone Fixation Element Relative to the Sleeve as Recited in Claim 19

It is respectfully submitted that Fixel does not cure the deficiencies of Durham in view of Lawes as discussed above in regard to claim 19. Since claims 28 and 29 depend from and include all of the limitations of claim 19, it is respectfully submitted that claims 28 and 29 are not rendered obvious by Durham in view of Lawes and in further view of Fixel and that the rejection of these claims should be reversed.

IV. The Rejection of Claims 30, 32 and 39 as Obvious Over Durham in View of Lawes and Further in View of Bresina Should be Reversed

A. The Examiner's Rejection

In the Final Office Action, claims 30, 32 and 39 were rejected under 35 U.S.C. § 103(a) as obvious over Durham in view of Lawes and further in view of Bresina. *11/18/08 Office Action*, p. 6.

- B. The References Do Not Disclose an Interior Surface Profile of a Sliding Sleeve Configured to Receive the Shaft of a Bone Fixation Element While Permitting Free Rotation of the Bone Fixation Element Relative to the Sleeve and a Locking Mechanism to Selectively Lock Rotation of the Bone Fixation Element Relative to the Sleeve as Recited in Claims 19 and 37
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It is respectfully submitted that Bresina does not cure the deficiencies of Durham in view of Lawes as discussed above in regard to claims 19 and 37. Since claims 30, 32 and 39 depend from and include all of the limitations of claims 19 and 37, respectively, it is respectfully submitted that these claims are not rendered obvious by Durham in view of Lawes and further in view of Bresina and that the rejection of these claims should be withdrawn.

- V. The Rejection of Claim 33 as Obvious Over Durham in View of Lawes and Further in View of Frigg Should be Reversed
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- A. The Examiner's Rejection

In the Final Office Action, claim 33 was rejected under 35 U.S.C. § 103(a) as obvious over Durham in view of Lawes and further in view of Frigg. *11/18/08 Office Action*, p. 6.

- B. The References Do Not Disclose an Interior Surface Profile of a Sliding Sleeve Configured to Receive the Shaft of a Bone Fixation Element While Permitting Free Rotation of the Bone Fixation Element Relative to the Sleeve and a Locking Mechanism to Selectively Lock Rotation of the Bone Fixation Element Relative to the Sleeve as Recited in Claim 19
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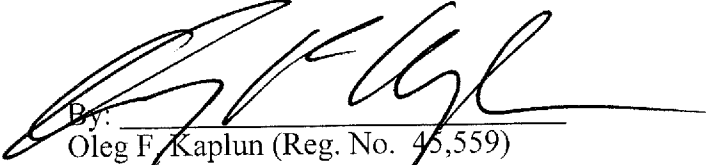
It is respectfully submitted that Frigg does not cure the deficiencies of Durham in view of Lawes as discussed above in regard to claim 19. Since claim 33 depends from and includes all of the limitations of claim 19, it is respectfully submitted that this claim is not rendered obvious by Durham in view of Lawes and Frigg and that the rejection of this claim should be withdrawn.

4. Conclusion

For the reasons set forth above, Appellants respectfully request that the Board reverse the final rejections of the claims by the Examiner under 35 U.S.C. § 103(a) and indicate that claims 19 - 40 are allowable.

Respectfully submitted,

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CLAIMS APPENDIX

19. (Previously presented) A device for the treatment of femoral fractures comprising:

an intramedullary pin having a first longitudinal axis, a proximal portion, a distal portion, and at least one transverse opening through the proximal portion of the pin, the at least one transverse opening forming an oblique angle with the first longitudinal axis and having a non-circular cross-section;

a bone fixation element having a second longitudinal axis, a first end, a second end, and a shaft, the first end configured and dimensioned to engage bone in the femoral head,

a sliding sleeve having a central bore, an interior surface profile, and an exterior surface profile, the central bore and interior surface profile configured to receive the shaft of the bone fixation element while permitting free rotation of the bone fixation element relative to the sleeve, and the exterior surface profile having at least a portion with a non-circular cross-section adapted to mate with the non-circular cross-section of the transverse opening, thereby prevention rotation of the sleeve with respect to the intramedullary pin; and

a locking mechanism configured and adapted to selectively lock rotation of the bone fixation element relative to the sleeve when in a first position and permit free rotation of the bone fixation element relative to the sleeve when in a second position.

20. (Previously presented) The device of claim 19, wherein the bone fixation element, sliding sleeve and locking mechanism are adapted for insertion through the transverse opening in the pin as a single preassembled unit.

21. (Previously presented) The device of claim 19, wherein the second end of the bone fixation element includes a longitudinal bore.

22. (Previously presented) The device of claim 21, wherein the longitudinal bore at the second end of the bone fixation element is at least partially threaded.

23. (Previously presented) The device of claim 22, wherein the locking mechanism is a fixing screw having a screw head with a diameter D and a screw shank with a diameter d having an outside thread, where $D > d$.

24. (Previously presented) The device of claim 23, wherein the outside thread of the fixing screw shank corresponds to the threaded bore of the bone fixation element, and progressive tightening of the fixing screw within the threaded bore rotationally locks the bone fixation element with the sliding sleeve, thereby preventing rotation of the bone fixation element relative to the sliding sleeve.

25. (Previously presented) The device of claim 19, wherein the bone fixation element is axially fixed relative to the sliding sleeve.

26. (Previously presented) The device of claim 25, wherein the shaft of the bone fixation element includes a first annular groove and the internal surface profile of the sliding sleeve includes a second annular groove, and a ring element engages both the first and second annular grooves to prevent axial displacement of the shaft relative to the sliding sleeve.

27. (Previously presented) The device of claim 19, wherein a rear end of the sliding sleeve extends a distance x past the second end of the bone fixation element, where x is at least 0.01 mm.

28. (Previously presented) The device of claim 19, wherein the second end of the bone fixation element includes an externally threaded portion.

29. (Previously presented) The device of claim 28, wherein the locking mechanism is a nut with an internal thread that corresponds to the externally threaded portion at the second end of the bone fixation element.

30. (Previously presented) The device of claim 19, wherein the first end of the bone fixation element includes a helical blade.

31. (Previously presented) The device of claim 19, wherein the first end of the bone fixation element includes a screw thread, a chisel, a pin, a T-section or a double T-section.

32. (Previously presented) The device of claim 19, wherein the first end of the bone fixation element includes a plurality of helical blades.

33. (Previously presented) The device of claim 30, wherein the helical blade has a pitch of at least 50 mm.

34. (Previously presented) The device of claim 19, wherein the locking mechanism is adapted to limit axial displacement of the sliding sleeve relative to the intramedullary pin.

35. (Previously presented) The device of claim 19, wherein the bone fixation element is a screw.

36. (Previously presented) The device of claim 19, wherein the external surface profile of the sliding sleeve includes a longitudinal projection that mates with a longitudinal recess in the transverse opening.

37. (Previously Presented) A device for the treatment of femoral fractures comprising:

an intramedullary pin having a first longitudinal axis, a proximal portion, a distal portion, and at least one transverse opening through the proximal portion of the pin, the at least one transverse opening forming an oblique angle with the first longitudinal axis and having a non-circular cross-section;

a cross-member configured for insertion through the transverse opening to engage bone in the femoral head, the cross-member including:

a sliding sleeve having a central bore, a circular interior surface profile, and a non-circular exterior surface profile, the exterior surface profile adapted to mate with the non-circular cross-section of the transverse opening, thereby preventing rotation of the sleeve with respect to the intramedullary pin,

a bone fixation element having a first end, a second end, and a shaft, the first end configured and dimensioned to engage bone in the femoral head, and the shaft configured and dimensioned for free rotation within the central bore of the sliding sleeve, and

a locking mechanism configured and adapted to selectively lock rotation of the bone fixing element relative to the sleeve when in a first position and permit free rotation of the bone

fixing element relative to the sleeve when in a second position.

38. (Previously presented) The device of claim 37, wherein the cross-member is adapted for insertion through the transverse opening in the pin as a single preassembled unit.

39. (Previously presented) The device of claim 37, wherein the first end of the bone fixation element includes a helical blade.

40. (Previously presented) The device of claim 37, wherein the bone fixation element is a screw.